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# In the Supreme Court of the United States

OCTOBER TERM, 1959

No. 654

DYESTUFFS & CHEMICALS, INC., PETITIONER

*v.*

ARTHUR S. FLEMMING, SECRETARY OF HEALTH, EDUCATION, AND WELFARE

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT*

## BRIEF FOR THE RESPONDENT IN OPPOSITION

### OPINION BELOW

The opinion of the Court of Appeals (Pet. App.) is reported at 271 F. 2d 281.

### JURISDICTION

The judgment of the Court of Appeals was entered on Oct 30, 1959 (R. 107). The petition for a writ of certiorari was filed on January 22, 1960. The jurisdiction of this Court is invoked under 28 U.S.C. 1254 (1).

### QUESTION PRESENTED

Before the decision of this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, petitioner had filed objections to removal by respondent of four toxic

coal-tar colors from the harmless list; these objections were all on grounds held invalid or irrelevant by this Court's decision. Some two months after the Court's ruling, the administrative order of removal, which had been stayed pending decision in the *Florida Citrus Exchange* case, was declared effective without a public hearing.

The question presented, for the first time in this Court, is whether it was error to promulgate the order at that time without a public hearing to allow petitioner to present further objections, although (a) no such further objections were ever filed, (b) none was specified or brought to the attention of the administrators before the order was promulgated, and (c) the statutory time for filing had long expired.

## STATUTES INVOLVED

The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 1049, 1055, as amended, 70 Stat. 919 (21 U.S.C. 301, *et seq.*), provides in pertinent part as follows:

SECTION 406(b)

* * * * *

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents. [21 U.S.C. 346(b).]

SECTION 701(e)

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section * * * 406 (a) or (b), * * * 504, or 604, of this Act shall be begun by a proposal made (A) by

the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due

notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. * * * [21 U.S.C. 371(e).]

* * * * *

**STATEMENT**

On January 24, 1957, the Deputy Commissioner of Food and Drugs published a notice of the Food and Drug Administration's proposal to amend its regulations listing coal-tar colors which are "harmless and suitable for use in food" (Section 406(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346 (b)), 22 F.R. 478 (R. 1), by removing FD&C Yellow No. 1, FD&C Yellow No. 2, FD&C Yellow No. 3 and FD&C Yellow No. 4, from the approved list for unrestricted use. This notice solicited the views and comments of interested parties.

After consideration of the comments received, including those of the Certified Color Industry Committee (R. 35–39) of which petitioner is a member, the Commissioner, on May 4, 1957, published an Order removing the colors in question from the approved food, drug, and cosmetic color list, 22 F.R. 3173 (R. 40), because they "are not harmless and suitable for use within the meaning of" the color certification provisions of the Act. This Order was to become effective 90 days after publication, unless stayed by the filing of proper objections (Section 701(e), 21 U.S.C. 371(e)).

On May 27, 1957, within the 30 days allowed by law, the Certified Color Industry Committee filed objections to the Order, stating the grounds therefor, as required by the statute (Section 701(e)(2), 21 U.S.C. 371(e)

(2)), and requesting a public hearing (R. 41–45). The grounds stated were as follows:

> 1. The colors in question are useful in the coloring of food and drugs (R. 42).
>
> 2. Pharmacological tests show that the level at which these colors produce adverse physiological effects is far in excess of their actual level of use in the human diet. There is therefore no adequate evidence of potential injury (R. 43).[1]
>
> 3. The reasonably anticipated uses of the four colors do not justify any fear of injury from their use (R. 43).
>
> 4. Rather than delist these colors completely, the Commissioner should establish tolerances for their use in oleomargarine and butter (R. 44–45).

In July 1957, after the objections had been filed, the Court of Appeals for the Fifth Circuit decided *Florida Citrus Exchange* v. *Folsom*, 246 F. 2d 850. Pending certiorari to review that judgment, delisting of the four yellow colors was stayed by administrative action, 22 F.R. 6613, August 17, 1957 (R. 46). On December 15, 1958, this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, reversed the judgment of the Fifth Circuit. It held that, "where a coal-tar color is not harmless, it is not to be certified" (p. 167), and that the Secretary "is without power to permit the use of harmful coal-tar colors in specific foods through a system of tolerances" (p. 166). Petitioner now ad-

[1] The pharmacological studies referred to in the objections were conducted in the Food and Drug Administration's scientific laboratories.

mits (Pet. 6) that "the only factual issue which petitioner had considered or contested in its 1957 objections became irrelevant" when *Florida Citrus* was decided.

On February 6, 1959, the Deputy Commissioner of Food and Drugs published the "Final Order" delisting these colors, 24 F.R. 883 (R. 47). The Order recited the history of the delisting proceeding, and explained that, since under this Court's decision in *Florida Citrus* the Department of Health, Education and Welfare could not establish a tolerance for a toxic color, no purpose could be served by holding a public hearing on objections seeking the promulgation of regulations that were beyond the Department's authority.

On May 6, 1959, the petitioner filed in the Court of Appeals for the Eighth Circuit a petition for review of the Food and Drug Administration's Order. As grounds, that petition stated, in paragraph 3 (R. 49):

> Under Section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)), said Secretary is required, upon request, to hold a public hearing upon the proposed issuance, amendment or repeal of any regulation under Section 406(b) and other sections of the Act. No public hearing has been held upon the proposed deletion of FD&C Yellows 3 and 4 from the list of colors certified for use in food color although public hearing was duly requested, and the Secretary, by his order of February 6, 1959, has refused to hold the requested hearing.

The Court of Appeals held that the statute does not unconditionally require a hearing, upon the mere filing

of objections, regardless of the validity of the filed objections. It said that where "it is perfectly clear that petitioner's appeal for a hearing contains nothing material and the objections stated do not abrogate the legality of the Order attacked, no hearing is required by law" (Pet. App. 9a). Finding that under *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, "each of the objections set forth by the petitioner must be held inadequate to prevent the removal of the coal tar colors in question from the 'harmless' list" (Pet. App. 7a), the Court of Appeals affirmed the Department's order and dismissed the petition for review (R. 107, Pet. App. 14a–15a).

## ARGUMENT

This petition for certiorari has abandoned the only issue raised in the petition for review filed in the Court of Appeals (R. 48–50). There, petitioner urged that, under Section 701(e) of the Federal Food, Drug and Cosmetic Act, the Secretary was required automatically to hold a hearing on the basis of the objections and request previously filed by petitioner. See *supra*, p. 6. Petitioner now admits (Pet. 6) that its 1957 objections are irrelevant under the ruling of this Court in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153. And, it now concedes (Pet. 7) that under *Denver Union Stock Yard Co.* v. *Producers Livestock Marketing Association*, 356 U.S. 282, and *United States* v. *Storer Broadcasting Co.*, 351 U.S. 192 (cases it sought to distinguish below), a public hearing need not be held when the grounds upon which the hearing

is requested are, as a matter of law, not relevant or material to the proper issues.

Petitioner now urges in this Court[2] that, nevertheless, the Order should not have been promulgated without a public hearing in order to give it an opportunity to present *new* objections to the "new" Order. One short answer is that, in the almost two-month period between this Court's decision in *Florida Citrus* and the promulgation of this Order, no attempt was made by petitioner to file such new objections.[3] Moreover, the Order of February 6, 1959, under review here, was

[2] After bringing and arguing its case on the theory that it was entitled to a hearing on the basis of its request, petitioner should not be permitted to change to a wholly new and inconsistent position. Cf. *Virginian Railway Co.* v. *Mullens*, 271 U.S. 220; *United States* v. *Tucker Truck Lines*, 344 U.S. 33; and *Unemployment Commission* v. *Aragon*, 329 U.S. 143, 155.

[3] At no time between December 15, 1958 and February 6, 1959, did the petitioner or the Industry Committee, of which it is a member, express a desire to file new objections, though a draft of the February 6 order was mailed in advance to the Industry Committee in late January, 1959. There is thus no substance to the claim that respondent's activities were so paced that petitioner had no opportunity to file new and pertinent objections (Pet. 8).

While petitioner asserts that its petition for review in the court below questioned the validity of the Order on the ground that it had not been permitted "to file relevant objections", and that it requested the Court of Appeals to direct the Department to consider objections it was prepared to make (Pet. 4), such objections were not in fact incorporated in the petition for review. Indications of the contemplated objections are found in the Court of Appeals opinion (Pet. App. 11a–14a). These were that the Order was not supported by substantial evidence and that the Department should be required to reconsider the *Florida Citrus* opinion in the light of subsequent administrative and legislative developments. These objections presented no basis for a hearing, as the Court of Appeals has held.

not a "new" order. The May 4, 1957 Order, to which petitioner filed timely objections, was stayed from August 7, 1957, until the February 6, 1959 Order. All the "new" order did was to act on the petitioner's objections in the light of this Court's December 1958 opinion in *Florida Citrus*. The original "Proposal" (R. 1), the "Order Acting on the Proposal" (R. 40), the "Order Staying the Effectiveness of Amendment" (R. 46), and the "Final Order" (R. 47), are all part of the same delisting proceeding. Petitioner's statutory time (of 30 days) to file objections ran from the date of the "Order Acting on the Proposal", *i.e.*, May 4, 1957. (See Section 701(e)(2), *supra*, p. 3.) The fact that petitioner did not discover that the objections which it filed at that time were legally insufficient until the decision of this Court in *Florida Citrus* did not give it the right to file additional objections. Late discovery of the governing law is no basis for filing new objections after the statutory period for objections has expired.[1]

If petitioner believes that it still has reasonable grounds for establishing that Yellows 3 and 4 are "harmless and suitable for use", as this Court has interpreted that language in *Florida Citrus*, a remedy is available. It may petition the Secretary for the relisting of these colors and, upon the showing of

[1] The Second Circuit had issued its opinion, upholding the respondent's order relating to Red 32, on August 10, 1956. *Certified Color Industry Comm.* v. *Secretary of Health, Education and Welfare*, 236 F. 2d 866. The Fifth Circuit's opinion in the Red 32 case (reversed by this Court) was not issued until July 1957, after petitioner had filed its objections to the proposed order in this case (on May 27, 1957). *Supra*, pp. 4–5.

reasonable grounds, a new administrative proceeding, which may include both hearing and judicial review, must be held (Section 701(e), 21 U.S.C. 371(e)). But the right to challenge the delisting order of May 4, 1957, was lost when no legally valid objections were filed within the 30 days allowed by Congress in Section 701(e)(2).

To initiate a new proceeding for relisting Yellows 3 and 4, petitioner would have to show that the colors themselves are non-toxic. Nowhere in the petition for review, the brief below, or in the petition for certiorari is there any indication that petitioner has any evidence to refute the scientific studies on which the Secretary's Order was based. These studies plainly showed that the colors are not "harmless". Unless new evidence is developed, the colors cannot be retained on the "harmless" list, under the present statute.

The reference (Pet. 9) to the recent order of the Commissioner of Food and Drugs issued on January 8, 1960, 25 F.R. 143—as indicating that the Commissioner and the court below have distorted and misapplied this Court's opinion in *Florida Citrus Exchange, supra,* as dispensing with hearings—is without justification. That order did not purport to remove any coal-tar colors from any of the relevant lists; it merely provided that all "certificates" which had been issued for batches of the colors, including Yellows 3 and 4, *prior* to the effective date of their removal from the approved list, would cease to be effective on April 6, 1960. The objections referred to in the portion of the order quoted by the petitioner (Pet. 9–10) were filed by petitioner in an entirely different

proceeding in an attempt collaterally to attack the factual basis for this delisting order. Since the delisting order has been affirmed, it is not subject to attack except in the present proceeding (*City of Tacoma* v. *Taxpayers*, 357 U.S. 320, 324), or until it is set aside in a new proceeding as suggested above; and the Commissioner properly so ruled in his recent order. The portion of that order quoted by petitioner does not indicate that the respondent will refuse to hold a hearing when adequate grounds are stated in properly filed objections; it indicates only that the respondent will not hold hearings on legally invalid "objections" (such as belated efforts to attack a delisting order collaterally).

## CONCLUSION

For the foregoing reasons, it is submitted that this petition for a writ of certiorari should be denied.

Respectfully submitted.

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